IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOLOGIC, INC., a Delaware corporation; and CYTYC SURGICAL PRODUCTS, LLC, a Massachusetts limited liability company, Plaintiffs, v. MINERVA SURGICAL, INC., a Delaware corporation, Defendant.	Civil Action No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

For its Complaint against Minerva Surgical, Inc. ("Defendant" or "Minerva"), Plaintiffs Hologic, Inc. ("Hologic"), and Cytyc Surgical Products, LLC ("Cytyc"; collectively "Plaintiffs") by its attorneys, allege as follows:

NATURE OF THE ACTION

1. In this action, Plaintiffs Hologic and Cytyc allege that Defendant willfully infringed U.S. Patent No. 9,095,348 ("the '348 Patent" or "the Patent-in-Suit") and that it concealed its commercialization of its infringing product from Plaintiffs and the Court to avoid being held accountable for its unlawful activity.

PARTIES

2. Plaintiff Hologic is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Hologic is a leader in women's health care including diagnostics, screening, and imaging, as well as medical intervention and treatment. Hologic is the owner by assignment of the '348 Patent

3. Plaintiff Cytyc is a limited liability company organized and existing under the laws of the Commonwealth of Massachusetts with a principal place of business at 250 Campus Drive, Marlborough, Massachusetts, 01752. Cytyc is a leader in designing, developing, and selling medical devices for the treatment of excessive or abnormal endometrial bleeding. Cytyc is a wholly-owned subsidiary of Hologic.

4. On information and belief, Defendant Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 4255 Burton Drive, Santa Clara, CA 95054.

JURISDICTION AND VENUE

5. This action arises under the Patent Laws of the United States, Title 35 of the United States Code.

6. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over the Defendant. On information and belief, Defendant has had systematic and continuous contacts with this District, regularly transacts business within this District, and regularly avails itself of the benefits of this District. On information and belief, Defendant, directly or through intermediaries (including sales agents and others), uses, offers for sale, sells, imports and/or distributes to others for such purposes, endometrial ablation products for the treatment of abnormal uterine bleeding, in the United States and this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b)-(c) as, among other reasons, Defendant is subject to personal jurisdiction in this District and a substantial part of the events giving rise to the claims occurred in this District.

BACKGROUND

A. Overview Of Endometrial Ablation

9. The '348 Patent relates to the treatment of "menorrhagia," *i.e.*, menstrual bleeding that is abnormally heavy in amount or duration. One treatment for this condition is a transcervical surgical technique, known as endometrial ablation, in which the lining of the uterus is destroyed to prevent further bleeding, such as by using heat, sub-zero temperatures, or electrical energy. In the early-1990s, physicians used "first generation" endometrial ablation instruments such as an electrified metal ball (a "roller ball") or wire loop to burn away the endometrial lining of the uterus. These techniques were effective but lengthy, often taking 30 to 50 minutes, because the physician had to move the instrument carefully over the entire inner surface of the uterus to ensure complete removal of the endometrial lining, bit-by-bit. They also presented serious risks to the patient, *e.g.*, electrocution of nearby organs. Further risks were presented by the need to distend (inflate) the uterus with a potentially toxic fluid, requiring control of the fluid pressure to avoid forcing fluid into the bloodstream via the vessels in the uterine wall (known as intravasation) or into the abdominal cavity via the fallopian tubes.

B. The NovaSure System Modernized Endometrial Ablation

10. In the late-1990s, while at Cytyc's predecessor-in-interest, Novacept, Inc. ("Novacept"), Mr. Csaba Truckai co-invented the NovaSure system, as a significant improvement over prior menorrhagia treatment techniques Mr. Truckai served as Novacept's VP of R&D and as its President. The NovaSure system, an embodiment of the '348 Patent, revolutionized endometrial ablation, making it safer and more effective than the previous roller ball or wire loop standards.

11. The NovaSure device's applicator treats the entire uterus simultaneously by conforming to its shape. The handpiece of the NovaSure system is pictured below:

The NovaSure device ablates the endometrial lining throughout the cavity in two minutes or less, 15 to 25 times faster than first generation techniques. It allowed the procedure to be performed in a physician's office, which is generally less expensive, less time consuming, more comfortable, and more convenient for the patient.

12. The NovaSure system has become the leading endometrial ablation system, having been used in the treatment of over three million patients.

C. The Patent-In-Suit

13. On August 4, 2015, the USPTO duly and legally issued the '348 Patent, entitled "Moisture Transport System for Contact Electrocoagulation" to Mr. Truckai, Russel M. Sampson, Stephanie Squarcia, Alfonso L. Ramirez, and Estela Hilario as inventors. A true and correct copy of the '348 Patent is attached as Exhibit A. Hologic is the assignee and lawful owner of all right, title, and interest in and to the '348 Patent.

14. The patented technology of the '348 Patent relates to systems for ablating the endometrial lining of uterine tissue to treat abnormal uterine bleeding.

15. The '348 Patent discloses and claims an endometrial ablation device generally comprising an elongate member, an applicator head coupled to the distal portion of the elongate

member, a handle coupled to the proximal portion (the portion closest to the physician user) of the elongate member, a deflecting mechanism within the applicator head, and an indicator mechanism. The deflecting mechanism is housed within the applicator head and, when actuated, causes the applicator head to expand and conform to the shape of the uterus. When the applicator head is deployed, the indicator mechanism indicates a dimension of the uterus.

D. Hologic Paid $325 Million To Buy Novacept And Its Patented Technology

16. In August 1998, Mr. Truckai executed a broad assignment to Novacept regarding U.S. Application No. 09/103,072, the application to which the '348 Patent claims priority. Mr. Truckai attested that he and other named inventors "invented certain new and useful improvements as described and set forth in the below-identified application for United States Letters Patent." For good and valuable consideration, he assigned all right, title, and interest in and to the inventions and the application, and any patents which may be granted based on that application, including continuations in whole or in part, among other things. Thus, Mr. Truckai assigned to Novacept his entire interest in the application that issued as the '348 Patent.

17. In 2004, Mr. Truckai sold Novacept to Cytyc for $325 million dollars. Novacept was a one-product company whose principal business was the design, development, manufacture, marketing, and sale of the NovaSure system. Novacept assigned its intellectual property to Cytyc consistent with Mr. Truckai's earlier assignments. Specifically, the parties acknowledged that subsequent patent prosecution would continue when Novacept assigned to Cytyc rights in any patent and patent applications, including any continuations, whether or not patented or reduced to practice. As part of the 2004 transaction, Cytyc acquired all right, title, and interest in the Novacept patent portfolio, and the inventors retained no rights to practice the technology that they sold.

18. In 2007, Hologic acquired Cytyc. The post-merger Hologic became the world's largest manufacturer of medical products directed to women.

E. Hologic's Subsequent Development And Investment In NovaSure

19. Hologic invested heavily in making NovaSure endometrial ablation the leading treatment for menorrhagia. Hologic invested millions of dollars and tens of thousands of hours in further research and development, clinical studies on safety and efficacy, and educational and training programs for physicians, subsequent to the Novacept acquisition.

20. Hologic undertook substantial clinical work to provide additional clinical data on the safety and efficacy of the NovaSure product. Hologic has continued to invest millions of dollars in clinical trials and research establishing the superior efficacy of NovaSure endometrial ablation over previous modes of treatment. Today, NovaSure endometrial ablation is the strongest brand in endometrial ablation—it is the most widely used and most reliable treatment option available for endometrial ablation.

F. Mr. Truckai Founded Minerva To Compete Directly With Hologic's NovaSure System With An Infringing Product

21. In 2008, Mr. Truckai formed Minerva, to create the Minerva Endometrial Ablation System ("EAS") to compete directly against the NovaSure system. Minerva has consistently held out Mr. Truckai as its founder.

22. Mr. Truckai developed the Minerva device. His design of the Minerva device was heavily influenced by his prior work on the patented NovaSure system, the very technology he had sold to Cytyc, and ultimately infringed patent rights transferred as part of that sale, including the '348 Patent.

23. Mr. Truckai was involved in virtually every aspect of the research, development, testing, clinical testing, and regulatory approval of Minerva's product. For example, he

facilitated testing by soliciting feedback from physicians and also directed engineers manufacturing the product. He provided specifications for the physical dimensions of the Plasma Formation Array ("PFA"), the portion of the device that expands in a woman's uterus like the NovaSure system. He revised the product's Software Requirements. He boasted that he was involved with every single product-specification document for the Minerva device.

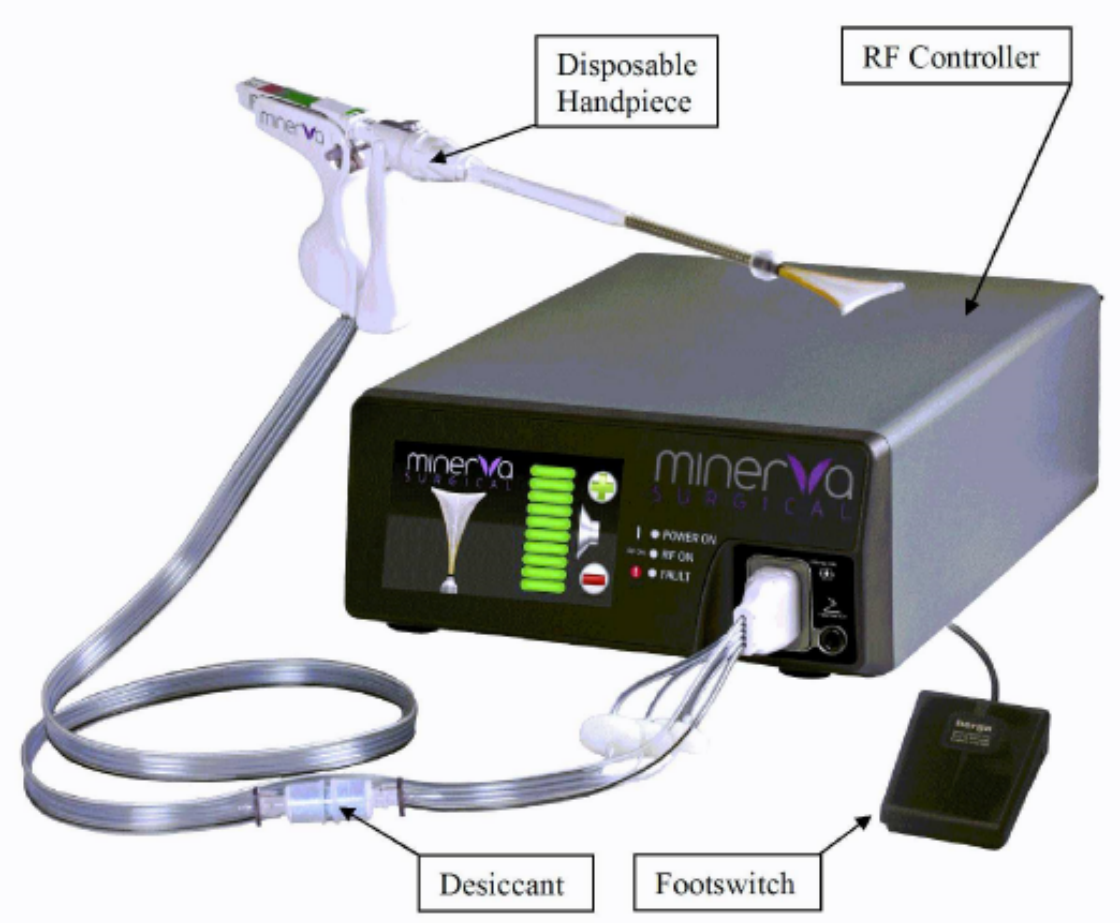
24. Mr. Truckai helped prepare Minerva's application for an investigational device exemption (IDE) from the FDA, represented Minerva during meetings with the FDA, provided input on Minerva's communications with the FDA, and provided input on patient selection for clinical trials.

25. Mr. Truckai served as Minerva's President and CEO at its founding, giving general direction to the company, putting a management team in place, raising capital, setting the strategic direction of the company, managing the company, and executing the company plan. According to Mr. Truckai, all of his job responsibilities were related to the Minerva EAS.

26. On information and belief, from 2008 and at least through 2019, Mr. Truckai also served on Minerva's Board of Directors where he assessed the direction of Minerva's business and owed Minerva a fiduciary duty. As a member of the Board, Mr. Truckai had input regarding all aspects of Minerva's business. On information and belief, Mr. Truckai owns Minerva stock.

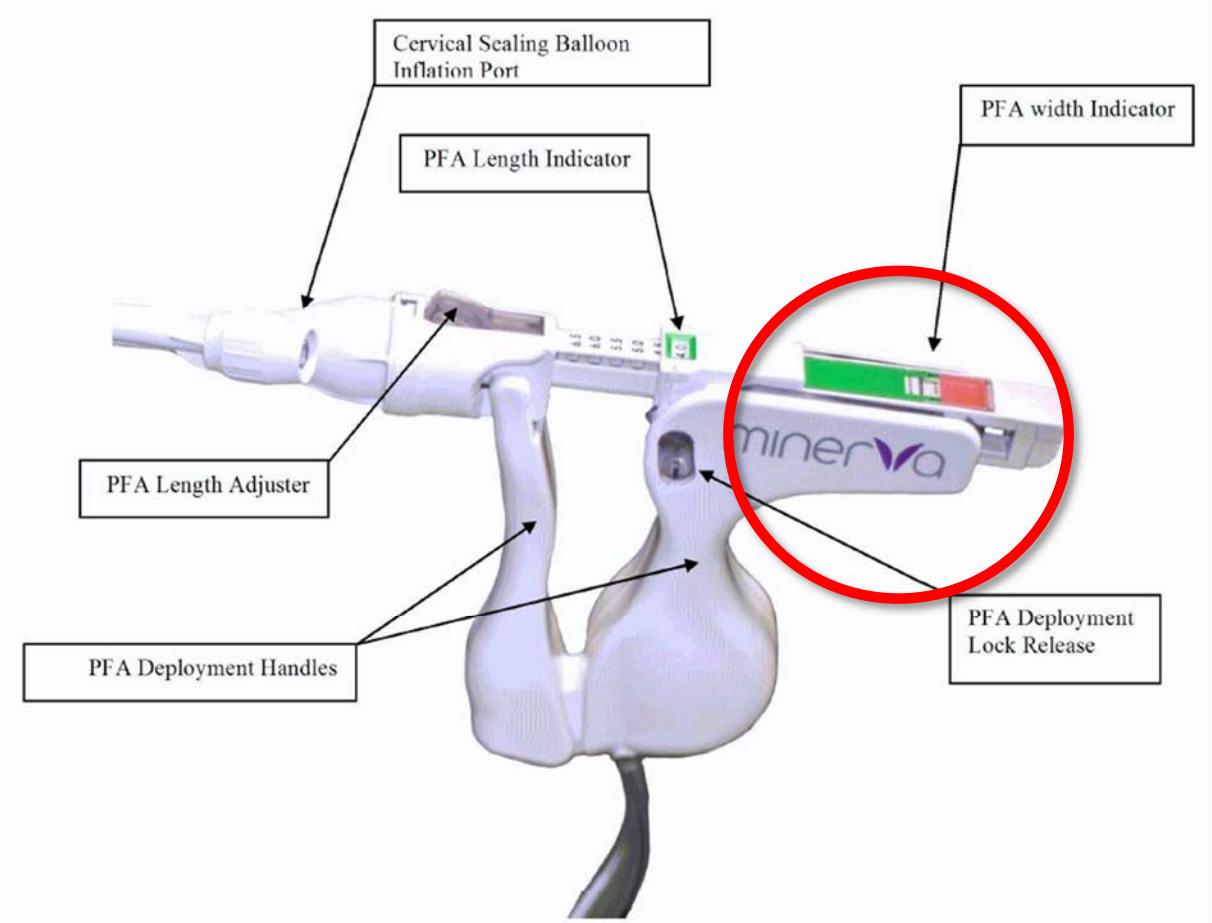
G. The Minerva Endometrial Ablation System ("EAS")

27. The Minerva EAS has two main components: a disposable handpiece and a radio frequency (RF) Controller:



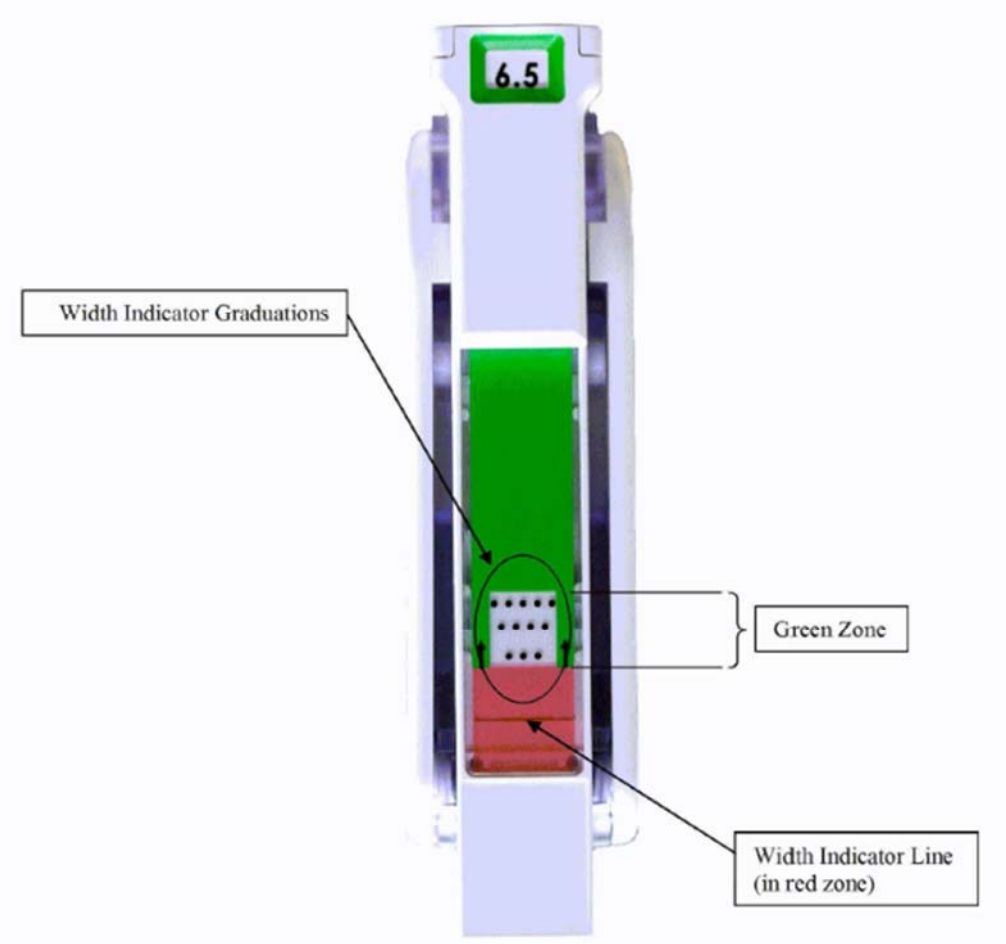
The distal end of the disposable handpiece consists of a PFA, which includes an expandable metal frame covered by a silicone membrane. The proximal end of the disposable handpiece includes a pivot-grip handle, which expands the metal frame to deploy the PFA, and a PFA Width Indicator, which indicates the expanded width of the PFA.

28. The PFA Width Indicator is pictured below:



The width of the expanded PFA reflects a dimension of the uterus, because the width of the Plasma Formation Array is limited by the width of the uterine cavity into which it is deployed. In other words, because the uterus presses against the PFA, the width of the PFA is a proxy for the width of the uterus.

26. The commercialized disposable handpiece includes a Red Area, a Green Area, and three rows of dots on the PFA Width Indicator—which Minerva calls "Width Indicator Graduations":



The width indicator on Minerva's EAS handpiece indicates when a patient's uterus is smaller than 2.5 cm. The Green Area indicates to physicians that the patient has a uterine width of at least 2.5 cm—and the Red Area indicates that the patient has a uterine width less than 2.5 cm—because Minerva's clinical data excludes women with uteri that are smaller than 2.5 cm. The rows of dots were added as a result of feedback from physicians. The dot scale on the width indicator indicates that the patient has a uterine width of approximately 3, 4, or 5 cm via the respective rows of 3, 4, and 5 dots.

H. The Prior Lawsuit And Trial

26. Hologic and Cytyc filed a complaint in this Court against Minerva in November 2015 for infringement of multiple patents including the '348 Patent (the "First Action").

29. Before trial, this Court ruled on summary judgment that Minerva's EAS product infringed the '348 Patent and that no reasonable juror could find that Minerva did not infringe.

30. The Court also rejected all of Minerva's invalidity defenses on summary judgment, finding that a jury trial on those defenses was unnecessary because no reasonable person could find for Minerva.

31. The Court also found that Minerva was barred from challenging validity due to assignor estoppel.

32. Following a July 2018 jury trial, the jury awarded lost profits and reasonable royalty damages to Hologic and Cytyc for Minerva's infringement of the '348 Patent.

33. The Court rejected Minerva's post-trial motions and entered judgment on June 3, 2019 against Minerva in the amount of $6,687,505.31.

34. A Panel of the Federal Circuit Court of Appeals rejected Minerva's appeal of the infringement and validity determinations relating to the '348 Patent and affirmed the judgment.

I. The Accused "New Pivot" Product

35. Unbeknownst to Hologic, Cytyc, and the Court at the time of the July 2018 trial, Minerva had been commercializing a modified hand piece since at least June 28, 2018 that Minerva had claimed did not infringe the '348 Patent. Minerva concealed its commercialization of that design to avoid having it adjudicated in the First Action.

36. The modified design was conceived by Minerva in 2016, after Minerva had been sued by Hologic and Cytyc in the First Action. Minerva developed prototypes of an EAS hand piece that incorporated one design change but was otherwise identical to the then-accused EAS hand piece. Throughout the First Action and through the July 2018 trial, Minerva maintained that this design change was merely a proposed change embodied in a prototype and not finalized into a commercial product.

37. The design change was made to the proximal and distal grips of the hand piece. Minerva's patent counsel referred to its proposed new handle as having a "New Pivot." This was indicated in writing on a piece of tape stuck to the device as shown below:

38. As the proximal and distal grips in Minerva's "New Pivot" handle are squeezed together, they slide toward one another, engaging two springs inside the proximal grip. The proximal and distal grips have an attachment point at a crescent-shaped plastic tab that receives the distal grip. When the grips are squeezed together, the top portions of the proximal and distal grips hinge or rotate towards one another at the plastic tab on the bottom of the distal grip.

J. Infringement Of The '348 Patent By The Accused "New Pivot" Product

39. In the First Action, it was found that Minerva's EAS satisfies all the elements of claim 1 of the '348 Patent and that it therefore infringed that claim. As discussed, Minerva's New Pivot device differs from the Minerva EAS in only one respect: the New Pivot handle.

Accordingly, Minerva is collaterally estopped from denying that the New Pivot device satisfies all the elements of claim 1 except for the requirement that the handles be "pivotally attached to one another at a pivot point."

40. The Minerva New Pivot device satisfies all the elements of at least claim 1 of the '348 Patent for the same reasons as Minerva's EAS device as found in the First Action.

41. Claim 1 of the '348 Patent requires in relevant part "a handle coupled to the proximal portion of the elongate member, wherein the handle comprises a frame, ***a proximal grip and a distal grip pivotally attached to one another at a pivot point***." (emphasis added). Minerva's prototype New Pivot handle includes a proximal grip and a distal grip that are pivotally attached to one another at a pivot point. As alleged above, the proximal and distal grips have an attachment point at a crescent-shaped plastic tab that receives the distal grip. The proximal and distal grips slide and then hinge or rotate towards one another along the plastic tab on the bottom of the distal grip. The grips are, therefore, allowed to slide and pivot relative to each other. The prototype with the New Pivot adds sliding motion, but the grips still have a pivot point and the pivot point is also the feature that keeps the grips attached to each other. On information and belief, Minerva's commercial New Pivot design operates in the same manner. In sum, despite the design change discussed above, the commercial New Pivot device infringed at least claim 1 of the '348 Patent.

42. Minerva's New Pivot prototype also infringes at least claim 1 of the '348 Patent under the doctrine of equivalents. Specifically, any difference between the claimed "proximal grip and a distal grip pivotally attached to one another at a pivot point" and Minerva's New Pivot handle in which the proximal grip and distal grip are attached at a tab and pivot at that tab, is insubstantial. Minerva's New Pivot design performs substantially the same function (expanding

and contracting the applicator head) in substantially the same way (squeezing together and releasing a handle comprised of two attached grips that rotate relative to one another), leading to substantially the same result (the expansion and contraction of the applicator head). The prototype was even labeled by Minerva's patent counsel as the "New Pivot."

43. In the First Action, Minerva argued that the New Pivot prototype was a non-infringing alternative to its then-accused EAS device, and it argued on summary judgment that prosecution history estoppel precluded Hologic and Cytyc from asserting that the New Pivot was infringing. The district court rejected Minerva's argument and Minerva did not appeal. Minerva is, therefore, collaterally estopped from arguing that the doctrine of equivalents is precluded.

K. Minerva's Concealment Of Its Commercialization Of The New Pivot Design And Its Willful Infringement

44. Minerva concealed its commercialization of the New Pivot product so that it would not be adjudged to infringe in the First Action. Indeed, despite ongoing obligations to Plaintiffs and the Court that it supplement its discovery in the First Action, Minerva concealed the fact that it intended to, and then actually did, commercialize its New Pivot design before the July 2018 trial. Minerva's concealment was not passive, as Hologic asked for supplemental discovery about Minerva's plans for its New Pivot design, but Minerva refused to provide the discovery and never corrected its assertions that the New Pivot design had not been commercialized. Minerva's misleading statements to Plaintiffs and the Court were willful, intentional, and deliberately designed to conceal its ongoing infringement, to delay resolution of Hologic's infringement claims, and to needlessly increase the cost of asserting the '348 Patent.

45. In the First Action, Minerva produced in discovery physical protypes of the New Pivot device and related documents in an effort to show that it was a non-infringing design-around to the asserted '348 Patent claims.

46. Minerva wasted much of expert discovery presenting this design-around theory, but abandoned that theory during the July 2018 trial, a tactic that it described as a "reasonable refinement" of its trial plan.

47. Months after the July 2018 trial, Hologic discovered that Minerva's "refinement" was actually part of obfuscation that Minerva perpetrated to hide the fact that it had commercialized the New Pivot design and was trying to keep that device out of the July 2018 trial.

48. Shortly before trial, on June 22, 2018, Plaintiffs asked Minerva to supplement its discovery regarding the New Pivot device. Minerva objected on relevance grounds because that device "is not currently in the market." Minerva's assertion was profoundly misleading, as it purportedly launched its New Pivot device commercially less than a week later, on June 28, 2018, and never corrected its assertion. Plaintiffs did not learn about Minerva's commercial launch of its New Pivot device until October 2018.

49. Minerva's refusal to supplement was particularly misleading because, during discovery, Minerva testified that it had not completed verification and validation testing of the New Pivot device and not a single physician had looked at or tested its new handle. Minerva also confirmed in discovery that it had not applied for FDA clearance for this design. Despite its supplementation obligations, at no time did Minerva supplement the record with the actual facts around the testing that permitted it to commercialize the New Pivot device by June 28, 2018.

50. In fact, Minerva perpetrated its concealment not only on Plaintiffs, but the Court as well. On June 28, 2018, the Court ruled on the parties' summary judgment motions, including those directed to infringement of the New Pivot design. While the Court determined that prosecution history estoppel did not preclude Plaintiffs from asserting that the New Pivot design

infringed under the doctrine of equivalents, the Court ultimately declined to determine whether the New Pivot device infringed the '348 Patent because, "since the product is not being marketed," such a ruling would be an advisory opinion. Minerva began marketing and commercializing its New Pivot device no later than that very same day, yet it never corrected the Court.

51. At the trial in late-July 2018, Minerva continued to misleadingly call its New Pivot device a "prototype" that was to be distinguished from its "current commercial handle," even though, at the time, the New Pivot device was actually being commercialized as Minerva's current commercial hand piece. In addition, despite already having launched this new hand piece, Minerva's founder and board member, Mr. Truckai, told the jury under oath that he was "not aware of design-around." This was weeks after Minerva commercially launched the New Pivot device.

52. It was not until the middle of post-trial briefing months later that Minerva first revealed that it "started shipping its redesigned handpiece starting on June 28, 2018"—the same day the Court had ruled that this prototype "is not being marketed" and just days after Minerva had refused to provide discovery on this redesign "since the product is not being marketed."

53. Minerva's infringement of the '348 Patent with the New Pivot design has been willful because of at least the following: (i) Minerva's subterfuge in hiding its commercialization of the New Pivot design; (ii) its knowledge of the Court's summary judgment ruling that its EAS device infringed the asserted claim of the '348 Patent; (iii) its knowledge that the district court repeatedly rejected Minerva's claim constructions of the '348 Patent claims as well as all of its invalidity defenses; (iv) the fact that the only differences between that infringing product and the New Pivot design are superficial; and (v) the fact that Minerva asserted that the

New Pivot design did not include a "pivot" even though its own patent counsel labeled it with the term "New Pivot," among other facts alleged herein.

54. Furthermore, Minerva's concealment of its commercialization of the New Pivot design in the first litigation estops or otherwise precludes it from asserting in this case that the New Pivot design does not infringe the '348 patent.

COUNT I

(Defendant's Infringement of the '348 Patent)

55. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

56. On information and belief, Defendant has infringed the '348 Patent literally and under the doctrine of equivalents in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products that are covered by at least claims 1, 3, and 8-10 of the '348 Patent. On information and belief, such devices include, but are not limited to, the Minerva Endometrial Ablation System with the "New Pivot" design.

57. Defendant has had knowledge of the '348 Patent since at least 2016, and it knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of Minerva's Endometrial Ablation System with the "New Pivot" design would infringe one or more claims of the '348 Patent. On information and belief, Defendant was aware that Plaintiffs' NovaSure system embodied the claimed invention of the '348 Patent and knew or should have known that the Minerva Endometrial Ablation System with the "New Pivot" design infringed one or more claims of the '348 Patent due to their substantially similar designs. On information and belief, Minerva knew or should have known that the Minerva Endometrial Ablation System

with the "New Pivot" design infringed one or more claims of the '348 Patent for the reasons stated hereinabove.

58. On information and belief, Defendant's infringement has been and continues to be willful, entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

59. Minerva's conduct, including its concealment of its commercialization plans in order to avoid resolution of the New Pivot design's infringement in the First Action, makes this an exceptional case under 35 U.S.C. § 285. If Minerva had not concealed its commercialization plans and instead allowed the infringement of the New Pivot design to be adjudicated in the First Action, then this additional action would not have been necessary.

60. Minerva is estopped from challenging the validity of the '348 patent at least due to assignor estoppel and collateral estoppel. Minerva is also estopped or otherwise precluded from asserting that the New Pivot design does not infringe the '348 patent.

61. As a result of Defendant's infringement of the '348 Patent, Plaintiffs have suffered damages up to the expiration of the '348 Patent on November 19, 2018.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

1. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant has infringed one or more claims of the '348 Patent;

2. Judgment in favor of Plaintiffs Hologic and Cytyc, and against Defendant Minerva Surgical, Inc., that Defendant's infringement of the '348 Patent has been willful;

3. Judgment awarding Plaintiffs Hologic and Cytyc damages adequate to compensate for Defendant's infringement of the '348 Patent in an amount to be proven at trial,

including lost profits and reasonable royalty damages, together with pre-judgment and post-judgment interest and costs, as fixed by the Court;

4. Judgment enhancing the damages due to Defendant Minerva Surgical, Inc.'s willful infringement, pursuant to 35 U.S.C. § 284;

5. Judgment declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs Hologic and Cytyc their attorneys' fees and costs incurred in prosecuting their claims; and

6. Such other relief as this Court deems just and proper.

JURY DEMAND

Plaintiffs demand a trial by jury in this action on all issues so triable.

DATED: July 8, 2020

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